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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,318	07/01/2003	Sylvia G. Kachalsky	2094/0878/67656-A/JPW/FHB	4833

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

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11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,318	KACHALSKY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-23* is/are pending in the application.

4a) Of the above claim(s) *10 and 13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 4-7 and 11-12 have been amended and claims 2-3 have been cancelled as requested in the amendment filed on June 18, 2007. Following the amendment, claims 1 and 4-23 are pending in the instant application.

Claims 10 and 13-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 05, 2006.

Claims 1, 4-9 and 11-12 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. At pp.19-20 of the Response, Applicant presents explanations regarding Supplemental IDS allegedly filed with the Response. Applicant is advised that the filing of Letter from Andrew Chin and CD-ROM within Exhibit 1, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The documents submitted have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

4. Applicant's arguments filed on December 21, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 4-9 and 11-12 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 5 of Paper mailed on July 17, 2006.

Applicant traverses the rejection by stating that, "at least one specific utility for applicants' polynucleotides as now claimed is for diagnosis. [...]Expression of the STR50 gene expression arose after experiments which stimulate stroke, and the diagnostic utility of applicants' claimed polynucleotides for stroke is specific, substantial and credible" (14 of the Response). Applicant's argument has been given careful consideration but found not to be persuasive for reasons that follow.

At p. 34 of the instant specification, Example 1, it is disclosed that in an ischemia rat model (permanent occlusion of middle cerebral artery),

> "The novel gene STR50 was found to be up-regulated at 12 hours (2.1 folds in cortex, 2.5 folds in whole hemisphere), 24 hours (3.3 fold in cortex and 3 folds in whole hemisphere) and 48 hours (1.9 folds in cortex and 2.6 folds in whole hemisphere)".

It is important to point out that there is no disclosure of comparison to expression levels of other genes, or dynamics of expression of the same gene under different brain pathology or

any other standard scientifically appropriate positive/negative controls. Also, there is no sound scientific reasoning or reference to prior art to establish that the animal "stroke model" is an art-accepted animal model suitable for search and discovery of markers for brain ischemia. One readily appreciates that during artificial (or pathological) cerebral artery occlusion, many genes undergo differential expression as a part of natural physiological response to acute ischemic conditions. The instant specification fails to provide any factual evidence that the instant claimed STR50 polynucleotides of SEQ ID NO: 1 or SEQ ID NO: 3 are specifically associated with any physiological process related to stroke.

According to legal standard, a specification can meet the utility and enablement requirement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide (an "evidence"), or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan ("sound scientific reasoning"). Thus, the law requires that the patent application describes the utility of the claimed invention based on evidence or obviousness to one skilled in the art.

With regard to diagnosis of disease, in order for a polynucleotide to be useful, as asserted, for diagnosis of a disease, there must be a well established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in a sample that derived from tissue under experimental ischemia is not sufficient for establishing a utility in diagnosis of stroke in the absence of some information regarding a correlative or causal relationship between the expression of the claimed polynucleotides and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would

allow the claimed polynucleotide to be used in a diagnostic manner. Many genes are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in stroke affected tissue to the exclusion of normal tissue or is expressed in specific disclosed levels in diseased tissue compared to normal tissue (i.e. overexpression). The instant specification discloses that the claimed nucleic acids (gene STR50) were "up-regulated" at certain time points in rat brains during artificial coronary artery occlusion test and asserts the practical utility of the STR50 polynucleotides as markers for stroke. However, there is no disclosure of the normal range of distribution of STR50 in the brain, or of the critical levels of STR50 expression specifically associated with stroke. There is also no explanation as how to extrapolate results obtained in rat model to conditions associated with stroke in human subjects (which probably is the alternative goal that supports the asserted practical utility of the instant invention).

In the absence of any disclosed relationship between the claimed polynucleotides and stroke and the lack of any correlation between the specific expression levels of the claimed polynucleotides during brain ischemia, any information regarding STR50 brain tissue expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696. In the instant case, the disclosure does not present a specific and substantial utility that would support the requirement of 35 U.S.C. §101.

Thus for reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4-9 and 11-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 4 and 5 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 2-5 and 11-12 in section 7 of Paper mailed on July 17, 2006.

Applicant submits that amendments to claims 4 and 5 obviates this ground of rejection (p. 17 of the Response). However, claims 4 and 5, as currently presented encompass "homolog(s)" of polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 3, and as such, the instant rejection is maintained.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11 and 12, as amended, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12, as currently presented, are vague and indefinite as directed to polynucleotides "consisting of between 15 and 922 consecutive nucleotides" followed by a reference to the sequence within SEQ ID NO: 1 or SEQ ID NO: 3. The structure of the claimed molecular embodiments cannot be appraised because the length and position of the claimed segments are not obvious. If Applicant's intention is to claim fragments of at least 15 nucleotides of SEQ ID NO: 1 or SEQ ID NO: 3 or a polynucleotide consisting of nucleotides 15-922 of SEQ ID NO: 1, for example, then these structural limitations must be clearly present within the claim.

Conclusion

11. No claim is allowed.

12. This application contains claims 10 and 13-23 drawn to an invention nonelected with traverse in Paper filed on June 05, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

November 7, 2007